IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MONTANA

MISSOULA DIVISION

PATRICK D. VINION and RICHELLE VINION, husband and wife, and CLAYTON H. RIDDLE and ANGELA RIDDLE, husband and wife,	)	CV 03-202-M-DWM
Plaintiffs,	)	
vs.	)	ORDER
AMGEN INC. and IMMUNEX INC.,	)	
Defendants.	)	

I. Introduction

Plaintiffs Patrick Vinion and Clayton Riddle participated in a drug trial conducted by Dr. Alan Whitehouse in Spokane, Washington. Vinion and Riddle suffer from asbestosis, and the study was to determine whether the prescription biologic Enbrel® was effective in improving asbestosis symptoms. Plaintiffs allege that Defendants promised to provide a continued free supply of Enbrel after the study was completed if the drug proved effective against Plaintiffs' symptoms. The Court dismissed Plaintiffs' breach of contract and Montana Consumer Protection Act claims on Defendants' Rule 12(b)(6) motion.

Before the Court is Defendants' motion for summary judgment

on Plaintiffs' remaining claims of negligence, negligent and intentional misrepresentation, negligent and intentional infliction of emotional distress, and loss of consortium. Defendants contend that evidence compiled through discovery proves they never promised to provide Enbrel free of charge after the conclusion of the study. With no evidence of a promise, Defendants argue that there was no duty and Plaintiffs' tort claims must fail.

Also before the Court is Plaintiffs' motion for partial summary judgment on the issue of Dr. Whitehouse's agency. Plaintiffs argue that even if Defendants did not expressly promise to provide Plaintiffs post-study Enbrel free of charge, Dr. Whitehouse did, and he was Immunex and Amgen's actual or ostensible agent capable of binding them to his promise.

For the reasons that follow, Defendants' motion for summary judgment was granted by separate order.

II. Factual & Procedural Background

A. August 2004 Order

This Court considered Defendants' Rule 12(b)(6) motion to dismiss in August, 2004. The Court dismissed Plaintiffs' breach of contract claim. Plaintiffs' Montana Consumer Protection Act claim was also dismissed because Plaintiffs were not consumers or purchasers of Enbrel, and did not suffer financial or property damages contemplated under the Act.

Plaintiffs' tort claims remained viable because it was premature to conclude there was no evidence to support their theory. The Court concluded: "[Plaintiffs'] Complaint alleges that Dr. Ann Hayes, 'a medical doctor and a representative of Defendants,' told Dr. Whitehouse, who then told Plaintiffs, that they would be provided the drugs free of charge forever. This promise is the basis for all of Plaintiffs' claims . . . ." Order at 11 (citations omitted). Thus, it was clear that Plaintiffs' remaining claims were dependent on evidence of an enforceable promise to provide Plaintiffs with Enbrel free of charge indefinitely after the conclusion of the drug study.

B. Meeting Between Dr. Whitehouse, and Dr. Ann Hayes and Dennis Steindorf of Immunex

What was not clear when the motion to dismiss Plaintiffs' tort claims was denied, was exactly what representations Immunex, Amgen, or their representatives had made to Dr. Whitehouse, and what he in turn had passed on to Plaintiffs. Dr. Whitehouse had claimed in his affidavit that Dr. Hayes, a representative of Immunex, promised that Immunex would provide Enbrel after the study to those study participants who had shown a positive response to the drug. His affidavit claimed the promise was made at a face-to-face meeting with Dr. Hayes and another of Immunex's representatives, Dennis Steindorf. Now that Dr. Whitehouse, Dr. Hayes, and Dennis Steindorf have been deposed, it is uncontroverted that even if the three did discuss the prospect of

Immunex providing Enbrel post-study, they never discussed Immunex providing the drug *free of charge*.

The record shows that sometime around the summer or fall of 2000, Dr. Whitehouse and Immunex's Dr. Ann Hayes and Dennis Steindorf met in Spokane, Washington to discuss a clinical research study to test the drug Enbrel on asbestosis patients.

Dr. Whitehouse testified that during the discussion with Hayes and Steindorf, Hayes said "[i]f any person who participated in the study of Enbrel medically benefitted from the drug, Immunex would continue to provide the drug to that person on a 'compassionate use basis' after the study was concluded." Whitehouse Aff. at 2; Whitehouse Depo. at 11. Dr. Whitehouse modified this statement at his deposition, admitting that the term "compassionate use" was not used during his conversation with Dr. Hayes. Whitehouse Depo. at 153. Dr. Whitehouse acknowledged that there was no similar promise in writing from Immunex. Id. at 12.

When Dr. Whitehouse was asked whether Dr. Hayes represented that Enbrel would be provided free of charge when the study ended, he responded:

> The word free never came into the discussion at all. But the answer that I got, that I recall, was that would the company provide it if a patient got better when they were on Enbrel at the end of the study. And the answer was yes.

Id. at 58. When asked to clarify whether Dr. Hayes said it would

be provided without charge, Dr. Whitehouse testified: "No, not that I - - I don't recall that ever, nor do I recall the patients asking me that either." Id. Once again, later in his deposition, Dr. Whitehouse testified that he "never actually discussed with the patients whether it would be free or whether it would be available to them thereafter." Id. at 81. He said: "I think I assumed, and I suspect they did too, that that meant free. . . . I was never actually told that, no. And I never actually related it to them." Id. When asked again if he truly assumed that Enbrel would be provided free of charge, Dr. Whitehouse answered: "I think at some level I did, although consciously I didn't." Id. at 132. He explained that in his previous experiences with pharmaceutical companies, he had asked for drugs on a compassionate use basis and the company provided samples of the drugs free of charge so patients without insurance could continue to use them. Id. at 132-33.

Dr. Whitehouse testified that he could prescribe Enbrel off-label for Vinion, Riddle, and other study subjects after the study ended if he had documented its benefits for each individual patient. Id. at 59-60. Dr. Hayes confirmed this testimony. Hayes Depo. at 17. Whitehouse documented Enbrel's beneficial affect on Vinion and Riddle and wrote Vinion a prescription, but Vinion was unable to fill the prescription for Enbrel because his insurance would not pay for it and he could not afford it on his

own. Whitehouse Depo. at 67-69, 62.

Dr. Hayes testified that in her time with Immunex, a test drug was never extended to a study subject after the study was completed. Hayes Depo. at 15. According to Dr. Hayes, she would never have said that Immunex would provide Enbrel post-study free of charge because "that is illegal unless [the study subject is] under a protocol and receiving it as per protocol from the company as part of a study." Id. at 19.

Dennis Steindorf also testified that neither he nor Dr. Hayes made a promise that Immunex would provide post-study Enbrel free of charge. Steindorf Depo. at 43, 48-49, 92. He testified that the term "compassionate use," though previously and sometimes still used in the pharmaceutical industry, was an old term that has become "inappropriate today" since there is no mechanism by which to provide a test drug after a study is completed, outside of a study extension or other FDA approved system. Id. at 45.

C. Consent Form Signed by Plaintiffs

The only document signed by Plaintiffs is the "Research Subject Information and Consent Form" ("Consent Form"). By signing, study subjects like Plaintiffs gave their consent to receive Enbrel for 12 months at specific doses. D's Exh. 4 at 2. The form warned of potential risks, hazards, and discomforts, but also described potential benefits of participating in the study.

Id. at 5. Regarding the costs of participating in the study, the form stated:

> During this study, the study drug will be supplied by Immunex at no cost to you. Costs related to your medical care including expensive tests or procedures that may be specifically required by this clinical research study may be your responsibility. You should discuss this with your study doctor before agreeing to participate in this study.
> Your insurance may or may not pay for these charges.

Id. The form emphasized that each subject's participation was voluntary and each was free to withdraw without penalty or loss of medical care or available treatment. Id. at 6. It warned subjects that

> [t]he study doctor or Immunex Corporation may decide to withdraw you or terminate this clinical study for either medical or administrative reasons (e.g., because the research is not beneficial or the study resources are no longer available) at any time and without your consent. If the study is discontinued, the study doctor will notify you and your study doctor will advise you of available treatments that may be of benefit.

Id.

If study subjects had medical questions, the form directed them to contact Dr. Whitehouse. Id. at 7. However, if they had questions concerning their rights as a study subject, the form directed them to contact Western International Review Board. Id. Plaintiff Riddle signed the original Consent Form on February 28, 2001, and Plaintiff Vinion signed on February 21, 2001. Id. at 8; D's Exh. 19 at 593.

The Consent Form was apparently modified sometime after

Riddle and Vinion became study subjects. Exh. 4, Bates 733. The amended form indicated that subjects were consenting to treatment for "up to 2 years" rather than 12 months. Id. at Bates 734-35. The form stated: "If you show an improvement at either Month 6 or Month 12 you can continue on Enbrel for one more year for a total of 2 years." Id. at Bates 735. Riddle signed the amended Consent Form on February 19, 2002, and Vinion signed the amended form on March 27, 2002. Id. at Bates 741; D's Exh. 19 at Bates 595.

Neither the original Consent Form nor the amended form contained any indication that study subjects would be entitled to receive Enbrel after the study was terminated or after they were withdrawn from the study, even if they had shown a positive response to the drug.

II. Analysis

A. Summary Judgment Standard

As the moving party, Defendants bear the burden of establishing that there are no genuine issues of material fact and that they are entitled to judgment as a matter of law. Fed. R. Civ. P. 56©. Rule 56© provides:

> [Summary Judgment] shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.

Id. If a reasonable jury could return a verdict for the

nonmoving party based on the available admissible evidence, summary judgment should not be granted.

B. Discussion

Each of Plaintiffs' remaining claims hinge on whether there is evidence that Defendants promised to provide Enbrel free of charge after the study. It is undisputed that Plaintiffs can purchase Enbrel off-label with a prescription. Dr. Whitehouse testified that he has provided an off-label prescription in Vinion's case and is willing to provide a prescription for both Plaintiffs. Because Enbrel is available to the Plaintiffs, albeit at a cost, they can only show they have been damaged if they can show that Defendants breached a promise to provide the drug *free of charge*.

1. Plaintiffs' Motion for Leave to File a Motion for Reconsideration of the August 2004 Order

Plaintiffs ask this Court to reconsider its August 2004 Order, claiming that discovery revealed new material facts that undermine this Court's previous conclusions.[1] Local Rule 7.2 requires that a motion for leave be based on one of two criteria:

> (1) (A) the facts or applicable law are materially different from the facts or applicable law that the parties presented to the Court before entry of the order for which reconsideration is sought, and (B) despite the exercise of reasonable diligence, the party

[1]Local Rule 7.2 provides that no party may file a motion for reconsideration without prior leave of Court. Plaintiffs complied with the local rule by moving for leave to file a motion for reconsideration.

> applying for reconsideration did not know such fact or law before entry of the order; or (2) new material facts emerged or a change of the law occurred after entry of the order.

L.R. 7.2(b). Plaintiffs base their motion for leave on a material change in facts rather than law.

Plaintiffs offer evidence that the term "compassionate use" is still being used in the pharmaceutical industry today, and that Amgen employees have heard it used in the company and are aware of its use as it refers to providing drugs to study subjects who are unable to get them otherwise. See P's Mot. for Leave at 6-7. Plaintiffs also offer what they characterize as a "smoking gun"—an internal memo from Amgen employee Rose Hesselbrock to two other Amgen employees. In the memo, Hesselbrock indicated that she thought someone should explain to Dr. Whitehouse the company's "standard treatment of these patients from this point forward." She stated:

> Just a "heads up." This is a bit sensitive as Dr. Whitehouse was strongly encouraged in the early days of this study, and I'm not sure what verbal commitments may have been made to him. There may be some pushback in that respect.

See P's Mot. for Leave at 5. Plaintiffs also claim discovery revealed that Immunex's Standard Operating Procedures provided a means by which the company might "release clinical drug supplies to an investigator for a patient to be described as an emergency candidate or 'compassionate study' participant." See P's Br. at 6-7. Finally, Plaintiffs claim that Amgen entered into an

agreement with another doctor/investigator to continue to provide Enbrel to his study participants on a "compassionate use" basis. P's Br. at 10-11.

Plaintiffs contend this new evidence shows that promises were made to Dr. Whitehouse. However, none of Plaintiffs' new facts are material to the issue of whether there was a promise. Even if the term "compassionate use" has been or is being used in the pharmaceutical industry in general, or by Amgen in particular, that fact has no bearing on whether Amgen actually promised to provide the drugs free of charge to these specific Plaintiffs. Plaintiffs' evidence that "compassionate use" and "free of charge" are interchangeable is speculation. Similarly, the fact that Amgen may have entered into an agreement with another doctor/investigator to provide Enbrel to that doctor's patients on a "compassionate basis" is not relevant to the question of whether Amgen made a similar promise to Dr. Whitehouse and these Plaintiffs. Finally, as to the alleged "smoking gun," Rose Hesselbrock's internal memo reveals nothing more than her uncertainty as to what verbal commitments may have been made to Dr. Whitehouse. The fact that Immunex "strongly encouraged" Dr. Whitehouse to conduct the Enbrel study does not mean that its encouragement included a promise to continue providing the drug to study subjects indefinitely without charge.

Contrary to Plaintiffs' assertion, these new facts do not change the basis upon which the Court decided Defendants' motion to dismiss. Thus, there is no reason for this Court to reconsider its August 2004 Order.

2. Summary Judgment

a. Evidence of a Promise

The undisputed facts found in the deposition testimony, affidavits, and documentary evidence reveal that Defendants never promised to provide Plaintiffs with free Enbrel. There were three participants at the meeting where Plaintiffs allege a promise was made—Dr. Whitehouse, Dr. Hayes, and Dennis Steindorf. Although Dr. Whitehouse testified that Dr. Hayes promised to continue providing Enbrel post-study, none of the three testified that they discussed Immunex providing Enbrel *free of charge* after the study was complete. Dr. Whitehouse testified that "the word free never came into the discussion at all," and that Dr. Hayes never said Enbrel would be provided without charge. Whitehouse Depo. at 58. Dr. Whitehouse also testified that he didn't recall his patients ever asking whether the drug would be provided free of charge, and that he "never actually discussed with the patients whether it would be free or whether it would be available to them thereafter." Id. Dr. Hayes and Dennis Steindorf denied making a promise to provide Enbrel free of charge after the drug study. As Defendants point out, and as

this Court noted in its previous Order, there is no evidence to contradict this testimony. In fact, because it explicitly limits the study to between twelve months to 2 years with no option to continue on the drug afterwards, the Consent Form supports the testimony and directly contradicts Plaintiffs' allegations to the contrary.

Dr. Whitehouse also testified that although Dr. Hayes never explicitly promised Enbrel free of charge, he assumed that any provision of Enbrel after the study would be at no cost to Plaintiffs because Plaintiffs were unable to pay for the drug. However, Dr. Whitehouse's assumption is not evidence of an enforceable promise. See Carey v. Wallner, 223 Mont. 260, 265, 725 P.2d 557, 561 (1986) ("A unilateral mistake is not normally grounds for relief for the mistaken party . . . .").

b. Agency

Plaintiffs argue that the disputed issue of whether Dr. Whitehouse, rather than Defendants, told Plaintiffs that they would continue to receive Enbrel post-study free of charge should be enough to defeat summary judgment. This disputed issue is only material if there is evidence that Dr. Whitehouse was authorized by Immunex/Amgen as an actual or ostensible agent to make promises on their behalf.

Montana Code Annotated section 28-10-103 sets forth the distinction between an actual and an ostensible agent:

> An agency is actual when the agent is really employed by the principal. An agency is ostensible when the principal intentionally or by want of ordinary care causes a third person to believe another to be the principal's agent when that person is not really employed by the principal.

Mont. Code Ann. § 28-10-103(1).

There is no evidence to support a finding that Dr. Whitehouse was Defendants' actual agent. As stated in the August 2004 Order, the written agreement between Dr. Whitehouse and Defendants shows that Dr. Whitehouse's "relationship to Immunex in the performance of this Agreement is that of an independent contractor." See Order at 7; Contract at 6. The contract also proclaims: "This written Agreement constitutes the entire agreement between the parties, and no terms or understandings not contained in this Agreement shall be valid or binding unless contained in writing and signed by both parties." Id. Dr. Whitehouse agreed to be the principal investigator for the study, and as such to conduct the scientific and medical aspects of the study, document the drug's effect on participating patients, and produce clinical data for Defendants' review and use. Dr. Whitehouse had equal right and control with Defendants to terminate the study or withdraw patients at any time for medical or administrative reasons. There is insufficient material proof to support a finding that Defendants exercised such control over Dr. Whitehouse that he was an employee or agent.

Plaintiffs argue further that even if the written contract

and evidence of the relationship between Dr. Whitehouse and Defendants does not reveal an employer/employee relationship, the undisputed facts demonstrate that Dr. Whitehouse was Defendants' ostensible agent. There is no material proof that Defendants acted in such a way that would lead Plaintiffs to conclude that Dr. Whitehouse could speak for them. In fact, the documentary evidence demonstrates that Plaintiffs had actual notice that Dr. Whitehouse was only authorized to convey answers to medical questions, not questions regarding Plaintiffs' rights as study subjects. Exh. 4 at 7. Whether Plaintiffs were entitled to receive the drug after the study was completed is a question regarding their rights as study subjects. Plaintiffs could not look to Dr. Whitehouse for that information, but rather had been told to contact Defendants or Western International Review Board to determine their rights after the study ended. Finally, it is irrelevant whether Dr. Whitehouse held himself out as having the authority to make promises for Defendants, because only Defendants' actions could have conferred on him such authority. See Bellanger v. Am. Music Co., 2004 MT 392, ¶ 20, 325 Mont. 221, ¶ 20, 104 P.3d 1075, ¶ 20 ("As to ostensible agency, such does not exist unless there is an act of the *principal* which leads a third party to believe an agency exists . . . ." (emphasis added).).

III. Conclusion

There is no material proof that Defendants promised to provide Enbrel free of charge after the study, so Plaintiffs are unable to show that Defendants owed them a duty. Thus, Plaintiffs' remaining tort claims fail as a matter of law. Further, Dr. Whitehouse was not authorized as an actual or ostensible agent to bind Defendants with his representations. For these reasons, Defendants' motion for summary judgment was granted by separate order. Plaintiffs' motion for memorandum in support of the Court's previous order **(dkt #165)** is granted by virtue of this Memorandum.

Dated this 9th day of November, 2005.

/s/
Donald W. Molloy, Chief Judge
United States District Court